

Art Unit: 1625

DETAILED ACTION

The examiner has issued a supplementary restriction in order to clarify the groups.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3,5,7-8, 11, 12, 15, 17,18-23, 25, 26, 29, 36-42, 49-52 , 54 drawn to compounds and pharmaceutical compositions wherein it is a tricyclic ring i.e. Ra and Rb for a 6 membered carbocyclic ring, R2 is an alkyl or an alkyl substituted by an alkoxy, X is a alkylene chain, Z is C=O, and R1-1 is an alkyl , a phenyl , a -N(CH3)OCH3 or a cycloalkyl.

Group II, claim(s) 1,3, 9, 12, 18, 20-23, 25, 26, 29, 44-47 drawn to compounds and pharmaceutical compositions wherein Ra and Rb do not join together to form a tricyclic ring. (i.e. it is a bicyclic ring) and R2 is an alkyl or an alkyl substituted by an alkoxy, X is a alkylene chain, Z is C=O, and R1-1 is an alkyl , a phenyl , a -N(CH3)OCH3 or a cycloalkyl.

Group III, claim(s) 1-3, 5,7-9, 11,12, 15, 17-23, 25, 26 and 29, drawn to compounds not enclosed in group I or Group II above. A further election of a single disclosed species is required. This group may be subject to further restriction.

Group IV-VI, claim(s) 30, 43, 48, 53, 55, drawn to a method of inducing cytokine biosynthesis limited to the scope of one of the product groups given above. A further election of a single disclosed species is required for search purposes.

Group VII-IX, claim(s) 31, drawn to a method of treating a viral disease limited to the scope of one of the compound groups given above. A further election of a single disclosed species is required for search purposes.

Group X-XII, claim(s) 32, drawn to a method of treating a neoplastic disease limited to the scope of one of the compound groups given above. A further election of a single disclosed species is required for search purposes.

Art Unit: 1625

The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

(f) Markush Practice. The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) all alternatives have a common property or activity, **and**

(B)(1) a common structure is present, i.e., a significant structural element is shared by all of the alternatives, or

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

(ii) In paragraph (f)(i)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of the existing prior art. The structural element may be a single component or a combination of individual components linked to-gether.

The different R₁, R₂, R_A and R_B substituents have so many variables with the heterocyclic and non-hetero groupings, they have different bonding and properties, and have achieved a different status in the art, and is burdensome to search and hence are objected to as being drawn to an improper Markush group on the grounds of lack of a common nucleus. The terms R₁, R₂, R_A and R_B, are so broad in scope that a prior art reference anticipating the claims with respect to one member under 35 USC 102(b) would not render obvious the same claims under 35 USC 103a with respect to another member..

Applicants core can be a tricyclic or a bicyclic ring both of which are not a novel core.

A preliminary search on the core gave numerous iterations indicating that the core is not novel and is not applicants contribution over the prior art. See US 5756747 (already of record).

An attempt was made to call Mr. El-Hayek on 3/18/09 to request an oral election to the above restriction requirement, but the examiner could not get in touch with him.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

Art Unit: 1625

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Art Unit: 1625

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

May 7, 2009

Application/Control Number: 10/595,959

Page 6

Art Unit: 1625

/Rita J. Desai/

Primary Examiner, Art Unit 1625